

ABSTRACT

A process for synthesizing leflunomide from 5-methylisoxazole-4-carboxylic acid and 4-trifluoromethylaniline is provided. Further provided is the leflunomide prepared by the inventive process, which is substantially free of difficult-to-separate impurities often found in leflunomide prepared by known methods, including N-(4-trifluoromethylphenyl)-2-cyano-3-hydroxycrotonamide, 5-methyl-N-(4-methylphenyl)-isoxazole-4-carboxamide and N-(4-trifluoromethylphenyl)-3-methyl-isoxazole-4-carboxamide. The invention further provides pharmaceutical compositions and dosage forms containing highly pure leflunomide and methods of treating disease using the leflunomide.